

May 5, 2009

Roger Citron, R.Ph.  
Medicaid Pharmacist  
Montana DPHHS  
Via email: RCitron@mt.gov

Dear Mr. Citron:

Thank you for your interest in ALVESCO® (ciclesonide) Inhalation Aerosol. I'm responding to your medical inquiry forwarded by your Account Director, Scott Hylla, regarding:

- Product Dossier for ALVESCO Inhalation Aerosol

The enclosed information is supplied as a professional courtesy in response to your inquiry. It is intended to provide pertinent data that will assist you in forming your own conclusions and making your own decisions. This information is not intended to advocate any indication, dosage, or other claim that is not covered in the enclosed package insert.

Additionally, please find the enclosed customer satisfaction survey, regarding the content of the requested information, which will assist the medical information department in providing the best possible service to healthcare professionals. Please complete the survey and send it back to the Medical Information Department (either via fax or the enclosed envelope containing pre-paid postage) at your earliest convenience.

For additional information regarding ALVESCO Inhalation Aerosol, please visit our <http://www.alvesco.us/> website. Should you have any questions or need additional information, please contact us directly at 1-800-739-0565.

Thank you again for your interest in ALVESCO Inhalation Aerosol.

Sincerely,

Melissa Ibrahim, PharmD  
Specialist, Medical Information

CC: John G. Karafilidis, PharmD  
Enclosure: Package Insert-ALVESCO® (ciclesonide) Inhalation Aerosol  
2009-003711

## Product Dossier for ALVESCO® (ciclesonide) Inhalation Aerosol

Thank you for your request to receive an ALVESCO Inhalation Aerosol Product Dossier.

The attached pharmacoeconomic information is being provided to you, as requested, because you indicated that this information is needed to support your organization in your capacity as an economic decision maker, third party payer, or large scale purchaser. This pharmacoeconomic information should not be provided to prescribers for the purpose of making treatment decisions for their individual patients.

### Enclosures:

1. ALVESCO® (ciclesonide) Inhalation Aerosol Product Dossier [Binder and CD-Rom]. Marlborough, Mass: Sepracor Inc; September 2008.
2. Adachi M, Ishihara K, Inoue H, et al. Efficacy and safety of inhaled ciclesonide compared with chlorofluorocarbon beclomethasone dipropionate in adults with moderate to severe persistent asthma. *Respirology*. 2007;12:573-580.
3. ALVESCO® (ciclesonide) Inhalation Aerosol [package insert]. Marlborough, Mass: Sepracor Inc; July 2008.
4. Bateman, E, Karpel J, Casale T, Wenzel S, and Banerji D. Ciclesonide reduces the need for oral steroid use in adult patients with severe, persistent asthma. *Chest*. 2006;129:1176-1187.
5. Bateman E, Linnhof AE, Homik L, Freudensprung U, Smau L, Engelstatter R. Comparison of twice-daily inhaled ciclesonide and fluticasone propionate in patients with moderate-to-severe persistent asthma. *Pulm Pharmacol Ther*. 2008;21:264-275.
6. Berger WE, Bernstein DI, Kerwin E, Pedinoff A. Effects of ciclesonide 80 µg twice daily or 160 µg once daily in adults with mild-to-moderate asthma not using inhaled corticosteroids. Poster presented at: American College of Asthma, Allergy & Immunology; November 6-11<sup>th</sup>, 2008; Seattle, WA (Study 3031).
7. Bernstein DI, Berger WE, Pedinoff A, Kerwin E. Evaluation of safety outcomes of patients with mild-to-moderate asthma not using an inhaled corticosteroid treated with ciclesonide 80 µg twice daily or 160 µg once daily. Poster presented at: American College of Asthma, Allergy & Immunology; November 6-11<sup>th</sup>, 2008; Seattle, WA (Study 3031).
8. Buhl R, Vinkler I, Magyar P, et al. Comparable efficacy of ciclesonide once daily versus fluticasone propionate twice daily in asthma. *Pulm Pharmacol Ther*. 2006;19:404-412.
9. Chylack LT, Gross GN, Pedinoff A, et al. A randomized, controlled trial to investigate the effect of ciclesonide and beclomethasone dipropionate on eye lens opacity. *J Asthma*. 2008;45:893-902 (Study 3027).
10. Gelfand W, Georgitis JW, Noonan M, Ruff ME. Once-daily ciclesonide in children: efficacy and safety in asthma. *J Pediatr*. 2006;148:377-383.
11. Hansel TT, Benezet O, Kafé H, et al. A multinational, 12-week, randomized study comparing the efficacy and tolerability of ciclesonide and budesonide in patients with asthma. *Clin Ther*. 2006;28:906-920.

12. Kerwin E, Pedinoff A, Berger WE, Bernstein DI. Asthma control in adults with mild-to-moderate asthma not using an inhaled corticosteroid treated with ciclesonide 80 µg twice daily or 160 µg once daily. Poster presented at: American College of Asthma, Allergy & Immunology; November 6-11<sup>th</sup>, 2008; Seattle, WA (Study 3031).
13. Korenblat P, Weinstein SF, Noonan M, Meltzer EO. Evaluation of the safety and efficacy of ciclesonide 80 µg twice daily or 160 µg once daily in patients with mild-to-moderate asthma switched from a previous inhaled corticosteroid. Poster presented at: American College of Asthma, Allergy & Immunology; November 6-11<sup>th</sup>, 2008; Seattle, WA (Study 3030).
14. Lipworth BJ, Kaliner MA, LaForce CF, et al. Effect of ciclesonide and fluticasone on hypothalamic-pituitary-adrenal axis function in adults with mild-to-moderate persistent asthma. *Ann Allergy Asthma Immunol.* 2005;94:465-472.
15. Magnussen H, Hofman J, Staneta P, Lawo J-P, Hellwig M, Engelstatter R. Similar efficacy of ciclesonide once daily versus fluticasone propionate twice daily in patients with persistent asthma. *J Asthma.* 2007;44:555-563.
16. Meltzer EO, Korenblat P, Nayak A, Weinstein SF. Evaluation of safety outcomes of ciclesonide 80 µg twice daily or 160 µg once daily in mild-to-moderate asthma patients switched from a previous inhaled corticosteroid. Poster presented at: American College of Asthma, Allergy & Immunology; November 6-11<sup>th</sup>, 2008; Seattle, WA (Study 3030).
17. Niphadkar P, Jagannath J, Joshi JM, et al. Comparison of the efficacy of ciclesonide 160 µg QD and budesonide 200 µg BID in adults with persistent asthma: A phase III, randomized, double-dummy, open-label study. *Clin Ther.* 2005;27:1752-1763.
18. Pearlman DS, Berger WE, Kerwin E, LaForce C, Kundu S, Banerji D. Once-daily ciclesonide improves lung function and is well tolerated by patients with mild-to-moderate persistent asthma. *J Allergy Clin Immunol.* 2005;116:1206-1212.
19. Pedersen S, Garcia ML, Manjra A, Theron I, Engelstatter R. A comparative study of inhaled ciclesonide 160 µg/day with fluticasone propionate 176 µg/day in children with asthma. *Pediatr Pulmonol.* 2006. 41:954-961.
20. Skoner D, Maspero J, Banerji D and the Ciclesonide Pediatric Growth Study Group. Assessment of the long-term safety of inhaled ciclesonide on growth in children with asthma. *Pediatrics.* 2008;121(1): e-publication (e1-e14).
21. Szeffler S, Rohatagi S, Williams J, Lloyd M, Kundu S, Banerji D. Ciclesonide, a novel inhaled steroid, does not affect hypothalamic-pituitary-adrenal axis function in patients with moderate-to-severe persistent asthma. *Chest.* 2005;128:1104-1114.
22. Vermeulen JH, Gyurkovits K, Rauer H, Engelstätter R. Randomized comparison of the efficacy and safety of ciclesonide and budesonide in adolescents with severe asthma. *Respir Med.* 2007;101:2182-2191.
23. von Berg A, Engelstätter R, Minic P, et al. Comparison of the efficacy and safety of ciclesonide 160 µg once daily vs. budesonide 400 µg once daily in children with asthma. *Pediatr Allergy Immunol.* 2007;18:391-400.

24. Weinstein SF, Meltzer EO, LaForce C, Korenblat P. Assessment of maintenance of asthma control in patients with mild-to-moderate asthma switched from a previous inhaled corticosteroid to ciclesonide 80 µg twice daily or 160 µg once daily. Poster presented at: American College of Asthma, Allergy & Immunology; November 6-11<sup>th</sup>, 2008; Seattle, WA (Study 3030).